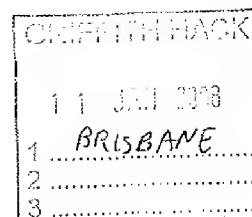


From the INTERNATIONAL BUREAU

**PCT**NOTIFICATION CONCERNING  
TRANSMITTAL OF COPY OF INTERNATIONAL  
PRELIMINARY REPORT ON PATENTABILITY  
(CHAPTER I OF THE PATENT COOPERATION  
TREATY)

(PCT Rule 44bis.1(c))

To:

GRIFFITH HACK  
Level 3  
509 St Kilda Road  
Melbourne, Victoria 3004  
AUSTRALIE

Date of mailing (day/month/year) 03 January 2008 (03.01.2008)		
Applicant's or agent's file reference BJN:FP23756		IMPORTANT NOTICE
International application No. PCT/AU2006/000841	International filing date (day/month/year) 16 June 2006 (16.06.2006)	
		Priority date (day/month/year) 16 June 2005 (16.06.2005)
Applicant BIONOMICS LIMITED et al		

The International Bureau transmits herewith a copy of the international preliminary report on patentability (Chapter I of the Patent Cooperation Treaty)

The International Bureau of WIPO  
34, chemin des Colombettes  
1211 Geneva 20, Switzerland

Authorized officer

Dorothee Mülhausen

Facsimile No. +41 22 338 82 70

e-mail: pt01.pct@wipo.int

# PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference BJN:FP23756	<b>FOR FURTHER ACTION</b>	See item 4 below
International application No. PCT/AU2006/000841	International filing date ( <i>day/month/year</i> ) 16 June 2006 (16.06.2006)	Priority date ( <i>day/month/year</i> ) 16 June 2005 (16.06.2005)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant BIONOMICS LIMITED		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

- |                                     |              |   |
|-------------------------------------|--------------|---|
| <input checked="" type="checkbox"/> | Box No. I    | Basis of the report   |
| <input type="checkbox"/>            | Box No. II   | Priority  |
| <input type="checkbox"/>            | Box No. III  | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability  |
| <input checked="" type="checkbox"/> | Box No. IV   | Lack of unity of invention  |
| <input checked="" type="checkbox"/> | Box No. V    | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/>            | Box No. VI   | Certain documents cited   |
| <input type="checkbox"/>            | Box No. VII  | Certain defects in the international application  |
| <input type="checkbox"/>            | Box No. VIII | Certain observations on the international application   |

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Date of issuance of this report 17 December 2007 (17.12.2007)
Facsimile No. +41 22 338 82 70	Authorized officer  <div style="text-align: center; font-weight: bold;">Dorothee Mülhausen</div> e-mail: pt01.pct@wipo.int

# PATENT COOPERATION TREATY

From the:  
INTERNATIONAL SEARCHING AUTHORITY

To:

Griffith Hack  
GPO Box 1285K  
MELBOURNE VIC 3001

## PCT

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing (day/month/year) <b>31 JUL 2006</b>	
Applicant's or agent's file reference <b>FP23756</b>	<b>FOR FURTHER ACTION</b> See paragraph 2 below
International application No. <b>PCT/AU2006/000841</b>	International filing date (day/month/year) <b>16 June 2006</b>
Priority date (day/month/year) <b>16 June 2005</b>	
International Patent Classification (IPC) or both national classification and IPC Int. Cl.  <b>C12N 15/01 (2006.01) C12Q 1/68 (2006.01) A61K 39/395 (2006/01) C07K 14/47 (2006/01)</b>	
Applicant <b>BIONOMICS LIMITED et al</b>	

1. This opinion contains indications relating to the following items:

- |                                     |              |  |
|-------------------------------------|--------------|--|
| <input checked="" type="checkbox"/> | Box No. I    | Basis of the opinion   |
| <input type="checkbox"/>            | Box No. II   | Priority   |
| <input type="checkbox"/>            | Box No. III  | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability   |
| <input checked="" type="checkbox"/> | Box No. IV   | Lack of unity of invention   |
| <input checked="" type="checkbox"/> | Box No. V    | Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/>            | Box No. VI   | Certain documents cited  |
| <input type="checkbox"/>            | Box No. VII  | Certain defects in the International application   |
| <input type="checkbox"/>            | Box No. VIII | Certain observations on the international application  |

### 2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: <a href="mailto:pct@ipaaustralia.gov.au">pct@ipaaustralia.gov.au</a> Facsimile No. (02) 6285 3929	Date of completion of this opinion  <b>19 July 2006</b>	Authorized Officer  <b>ALISTAIR BESTOW</b> Telephone No. (02) 6283 2450
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WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/AU2006/000841

Box No. I      Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:
  - ☒ The international application in the language in which it was filed
  - ☐ A translation of the international application into, \_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (under Rules 12.3(a) and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
  - a. type of material
    - ☒ a sequence listing
    - ☐ table(s) related to the sequence listing
  - b. format of material
    - ☐ on paper
    - ☒ in electronic form
  - c. time of filing/furnishing
    - ☐ contained in the international application as filed.
    - ☐ filed together with the international application in electronic form.
    - ☒ furnished subsequently to this Authority for the purposes of search.
3. ☒ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/AU2006/000841

Box No. IV Lack of unity of invention

1. ☐ In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has, within the applicable time limit:
- ☐ paid additional fees
  - ☐ paid additional fees under protest and, where applicable, the protest fee
  - ☐ paid additional fees under protest but the applicable protest fee was not paid
  - ☐ not paid additional fees
2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
- ☐ complied with
  - ☒ not complied with for the following reasons:

The claims are directed to 41 inventions, each invention being a specific variant of the SCN1A gene, as specified in Table 3. That amino acid mutations exist in SCN1A, and that they are associated with the diagnosis of an epilepsy syndrome is known. (see for example OHMORI, I., et. al. (2002) Significant correlation of the SCN1A mutations and severe myoclonic epilepsy in infancy. *Biochemical and Biophysical Research Communications* 295:17-23.) Therefore the fact that amino acid changes in the SCN1A polypeptide are associated with epilepsy, is not a special technical feature of the invention. Therefore, each SCN1A polypeptide comprising a different amino acid change is a separate invention, as specified in Table 3. However, as all inventions were searched without significant additional effort, all the inventions were considered for the purposes of this opinion.

4. Consequently, this opinion has been established in respect of the following parts of the international application:
- ☒ all parts
  - ☐ the parts relating to claims Nos.

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/AU2006/000841

**Box No. V**      **Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Claims 39	YES
	Claims 1-38, 40-60	NO
Inventive step (IS)	Claims 39	YES
	Claims 1-38, 40-60	NO
Industrial applicability (IA)	Claims 1 - 60.	YES
	Claims	NO

**2. Citations and explanations:**

Citations

D1 WO 2004/085674 A1 (BIONOMICS LIMITED) 7 October 2004.

D2 WO 2005/014863 A1 (BIONOMICS LIMITED) 17 February 2005

D3 FUJIWARA, T., et. al. (2003) *Brain* 126:531-46

D4 WO 2002/050096 A1 (BIONOMICS LIMITED) 27 June 2002

D5 WO 2002/006521 A1 (BIONOMICS LIMITED) 24 January 2002

D6 OHMORI, I., et. al. (2002) *Biochemical and Biophysical Research Communications* 295:17-23

Novelty (N) and Inventive Step (IS)

D1 discloses altered SCN1A subunits of mammalian voltage-gated sodium channel polypeptides (see claim 37) and their use in the diagnosis of SMEI in patients (see claim 1 - 26), methods of treating epilepsy including SMEI (see claims 53 - 60). In particular, D1 discloses an altered SCN1A subunit having the amino acid change A239T (see SEQ ID 31 and Table 3), which is also one of the specific amino acid changes being the subject of the present claims. Therefore claims 1 - 38 and 40 - 60 lack novelty and inventive step.

D2 discloses altered SCN1A subunits of mammalian voltage-gated sodium channel polypeptides (see claim 19) and their use in the diagnosis of SMEI in patients (see claim 1 - 7), methods of treating epilepsy including SMEI (see claims 42 - 50). In particular, D1 discloses an altered SCN1A subunit having the amino acid change W384X (see claim 19, SEQ ID 74 and Table 3), which is also one of the specific amino acid changes being the subject of the present claims. Therefore claims 1 - 38 and 40 - 60 lack novelty and inventive step.

D3 discusses mutations in SCN1A, and their association with epilepsy, but does not disclose or suggest the amino acid changes described in the present application. While D4, D5 and D6 disclose several amino acid changes in the SCN1A subunit of mammalian voltage-gated sodium channel polypeptides, (see Table 3 of D4, claim 8 of D5 and Table 2 of D6) and their association with epilepsy, it does not disclose or suggest the amino acid changes disclosed in the present application. Therefore the claims appear novel and inventive in view of either of D3, D4, D5 or D6.